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EXAMINER	
SCHWADRON, RONALD B	
ART UNIT	PAPER NUMBER
1644	42

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/323,060	Applicant(s) Comp
	Examiner Ron Schwadron, Ph.D.	Art Unit 1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☐ Responsive to communication(s) filed on _____.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-9, 11-13, and 19-21* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-6, 11-13, and 19* is/are rejected.

7) ☒ Claim(s) *7-9, 20, and 21* is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☒ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. Claims 1-9,11-13,19-21 are under consideration. Claim 3 has been amended.

RESPONSE TO APPLICANTS ARGUMENTS

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-6,11-13,19 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants arguments have been considered and deemed not persuasive.

The specification does not provide adequate written description of the claimed invention. The legal standard for sufficiency of a patent's (or a specification's) written description is whether that description "reasonably conveys to the artisan that the inventor had possession at that time of the. . .claimed subject matter", Vas-Cath, Inc. V. Mahurkar, 19 U.S.P.Q.2d 1111 (Fed. Cir. 1991). In the instant case, the specification does not convey to the artisan that the applicant had possession at the time of invention of the "inhibitor of an anticoagulant" as recited in the cl.

The instant claims encompass a method that uses an "inhibitor of an anticoagulant" wherein the anticoagulant is recited in the claims. However, the only "inhibitor of an anticoagulant" (wherein the anticoagulant is recited in the claims) disclosed in the specification is an antibody which binds the anticoagulant recited in the claims. The specification refers to undisclosed chemical inhibitors without identifying said agents. The claims encompass a vast genus of potential agents which could function as an "inhibitor of an anticoagulant" (wherein the anticoagulant is recited in the claims) while only disclosing antibodies which have that function. The claims could

potentially encompass the use of agonist peptides or mimotopes with the functional properties recited in the claim, but there is no disclosure of such agents in the specification. In view of the aforementioned problems regarding description of the claimed invention, the specification does not provide an adequate written description of the invention claimed herein. See The Regents of the University of California v. Eli Lilly and Company, 43 USPQ2d 1398, 1404-7 (Fed. Cir. 1997). In University of California v. Eli Lilly and Co., 39 U.S.P.Q.2d 1225 (Fed. Cir. 1995) the inventors claimed a genus of DNA species encoding insulin in different vertebrates or mammals, but had only described a single species of cDNA which encoded rat insulin. The court held that only the nucleic acids species described in the specification (i.e. nucleic acids encoding rat insulin) met the description requirement and that the inventors were not entitled to a claim encompassing a genus of nucleic acids encoding insulin from other vertebrates, mammals or humans, id. at 1240. In the instant case, the facts are similar to those disclosed in University of California v. Eli Lilly and Co. The Federal Circuit has held that if an inventor is "unable to envision the detailed constitution of a gene so as to distinguish it from other materials. . .conception has not been achieved until reduction to practice has occurred", Amgen, Inc. v. Chugai Pharmaceutical Co, Ltd., 18 U.S.P.Q.2d 1016 (Fed. Cir. 1991). Attention is also directed to the decision of The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated: The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate."). Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

Thus, as we have previously held, a cDNA is not defined or described by the mere name "cDNA," even if accompanied by the name of the protein that it encodes, but requires a kind of specificity usually achieved by means of the recitation of the sequence of nucleotides that make up the cDNA. See Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606.

Applicants has referred to a variety of different references that were published after the effective filing date of the instant application (eg. 7/24/92). These references are not germane to the instant rejection because they reflect the state of the art after the effective filing date of the

instant application. Regarding the analysis for compliance with written description under 35 U.S.C. 112, first paragraph, the MPEP section 2163, section 2 (page 2100-160 Rev. August 2001) states

The analysis of whether the specification complies with the written description requirement calls for the examiner to compare the scope of the claim with the scope of the description to determine whether applicant has demonstrated possession of the claimed invention. Such a review is conducted from the standpoint of one of skill in the art ***at the time the application was filed*** *(see, e.g., Wang Labs. v. Toshiba Corp., 993 F.2d 858, 865, 26 USPQ2d 1767, 1774 (Fed. Cir. 1993)) and should include a determination of the field of the invention and the level of skill and knowledge in the art. Generally, there is an inverse correlation between the level of skill and knowledge in the art and the specificity of disclosure necessary to satisfy the written description requirement. Information which is well known in the art need not be described in detail in the specification. See, e.g., Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1379-80, 231 USPQ 81, 90 (Fed. Cir. 1986).*

Thus, the Creasy et al. 1993 abstract, Griffin et al. 1993 abstract, Oosting et al. 1993 abstract, Nordfang et al 1993, Kristensen et al. (Sept 1992) and Xu et al. (1994) references are not relevant to the instant rejection because they disclose the state of the art after the effective filing date of the instant application.

Regarding applicants comments, the instant claims encompass a method that uses an "inhibitor of an anticoagulant" wherein the anticoagulant is recited in the claims. However, the only "inhibitor of an anticoagulant" (wherein the anticoagulant is recited in the claims) disclosed in the specification is an antibody which binds the anticoagulant recited in the claims. The specification refers to undisclosed chemical inhibitors without identifying said agents. The claims encompass a vast genus of potential agents which could function as an "inhibitor of an anticoagulant" (wherein the anticoagulant is recited in the claims) while only disclosing antibodies which have that function. The claims could potentially encompass the use of agonist peptides or mimotopes with the functional properties recited in the claim, but there is no disclosure of such agents in the specification. Regarding applicants comments on page 4 of the instant amendment it is noted that claims drawn to the method that uses antibody against protein C have been not included in the instant rejection. It is also noted that while the Board of appeals found the instant

claims enabled and free of the art, the Board did not address the issue of written description of the claimed invention.

Regarding applicants comments about antibodies, the instant rejection already states that the instant application provides written description of antibody which binds the anticoagulants recited in the claims (However, the only "inhibitor of an anticoagulant" (wherein the anticoagulant is recited in the claims) disclosed in the specification is an antibody which binds the anticoagulant recited in the claims.). The claims encompass a vast genus of potential agents which could function as an "inhibitor of an anticoagulant" (wherein the anticoagulant is recited in the claims) while only disclosing antibodies which have that function. The claims could potentially encompass the use of agonist peptides or mimotopes with the functional properties recited in the claim, but there is no disclosure of such agents in the specification. Regarding applicants comments about Broze, Jr (Sem. In Hematol.), said reference is drawn to a discussion of TFPI (Tissue factor pathway inhibitor). Said reference does not disclose an inhibitor of TFPI or any of the other anticoagulants disclosed in claim 1. Regarding applicants comments about Gene 1993 (Griffin et al.)said reference was published after the effective filing date of the instant application and therefore is not germane to the instant rejection. Furthermore, said reference refers to antisense inhibition of thrombin wherein thrombin is not an anticoagulant. The specification refers to undisclosed chemical inhibitors without identifying said agents.

While the instant application provides written description of antibodies which bind the anticoagulant molecules recited in claim 1, the claims encompass a vast genus of undisclosed inhibitors of said molecules. Regarding applicants comments, the only specific inhibitor of one of the molecules disclosed in the claims that is disclosed in the specification is an antibody. The references cited by applicant that are pertinent to the instant rejection (eg. published before effective filing date of the instant application) also fail to describe any molecule other than antibody which would function as an inhibitor of the anticoagulants recited in the claims. While the anticoagulants recited in the claims are known in the art, their inhibitors other than antibodies are not described in the specification. The Regents of the University of California v. Eli Lilly and Company (CAFC, July 1997) wherein is stated: The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. See In re Wilder, 736 F.2d 1516, 222 USPQ 369, 372-373 (Fed. Cir. 1984) (affirming rejection because the specification does "little more than outlin[e] goals appellants hope the claimed invention achieves and the problems the invention will hopefully ameliorate.").

Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

4. Claims 7-9, 20, 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. No claim is allowed.

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

7. Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Papers should be faxed to Group 1600 at (703) 308-4242.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Dr. Ron Schwadron whose telephone number is (703) 308-4680. The examiner can normally be reached Monday through Thursday from 7:30 to 6:00. A message may be left on the examiners voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ms. Christina Chan can be reached on (703) 308-3973. Any inquiry of a general nature or relating to the status of this application should be directed to

the Group ~~180~~ 1600 receptionist whose telephone number is (703) 308-0196.

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1800~~ 1600

Ron Schwadron, Ph.D.
Primary Examiner
Art Unit 1644